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PROSTATIC STENT AND DELIVERY SYSTEM

Technical Field

[0001] This invention relates to stents used to maintain a body lumen, such as the prostatic urethra, and to systems for delivering stents into these body lumens.

Background Information

[0002] Stents are a known class of medical device for expanding or maintaining an open lumen or passageway in various body cavities, vessels, or ducts. Stents have been employed, for example, in the urethra, the ureters, the biliary tract, the cervix, the rectum, the esophagus and blood vessels to relieve the pathological effects of constrictions occurring in these passageways.

[0003] Bladder obstruction arising from enlargement of the prostate gland in males is one of the most commonly encountered disorders in urology. The prostate gland lies under the bladder and surrounds the passageway known as the prostatic urethra, which transfers fluids from the bladder to the sphincter and ultimately outside the body. An enlarged prostate gland constricts the prostatic urethra leading to a condition known as benign prostatic hyperplasia ("BPH"). BPH causes a variety of obstructive symptoms, including urinary hesitancy, straining to void, decreased size and force of the urinary stream, and in extreme cases, complete urinary retention possibly leading to renal failure. A number of other irritating symptoms may also accompany BPH, including urinary frequency and urgency, nocturnal incontinence, and extreme discomfort.

[0004] Known stents used to combat BPH may not ensure patient safety and comfort. Indeed, existing stents, such as wire mesh stents, may become entangled with

prostate tissue leading to infection and discomfort. Under such conditions, prostate tissue often penetrates the perforations of the wire mesh stent rendering it difficult, if not impossible, to remove without surgical intervention. Other devices, such as Foley catheters are retained in the bladder by a balloon inflated with sterile water or saline. This necessitates use of a collection bag to catch fluids drained from the bladder, thereby reducing a patient's quality of life. In addition, many stents cannot accommodate unusually or abnormally shaped prostatic urethras or prostatic urethras of varying lengths and widths.

[0005] Also, internal forces from involuntary bodily functions (such as peristalsis and other secretory forces, as well as patient movement) may force some stents out of their intended position within the prostatic urethra. For instance, the bladder can exert intense pressure during urination, which tends to expel a stent positioned within the prostatic urethra. It is also possible that normal body motions, such as walking or running may displace a stent at this location.

Summary of the Invention

[0006] In one embodiment, the invention reduces the risk of infection/inflammation, while also maintaining patient comfort and preventing migration of the stent out of the prostatic urethra. According to one feature, the outer surfaces of the stent are smooth, and do not become entangled with and/or potentially infect internal body tissue. Structural features of certain embodiments of the invention, including a double funnel or hourglass configuration, ensure that the stent will not dislodge or migrate out of its intended position. According to another feature the stent is easy to insert, and should circumstances warrant, easily removed without the need for invasive surgery. In addition, the stent may be designed according to the individual needs of particular patients by tailoring its dimensions to accommodate prostatic urethras of various sizes and shapes.

[0007] One aspect of the invention relates to a collapsible and expandable stent including first and second terminal ends spaced apart from each other, a substantially smooth wall disposed between the first and second terminal ends and a lumen extending between the first and second terminal ends. Preferably, the stent is designed for use in the prostatic urethra of a male patient, and is constructed of flexible biocompatible materials such as elastomeric compounds. Materials like these combine rigidity with the softness necessary for patient stability and comfort. To help retain the stent in place in a body of a patient, at least one of the first and second terminal ends is wider than at least some portion of the wall disposed between the terminal ends.

[0008] To further help anchor the stent in the body, the first and second terminal ends may further include a retention ring having an elastic member. Where both the first and second terminal ends include retention rings, these retention rings are preferably aligned in a substantially parallel relationship. By varying the size of the retention rings, the stent can accommodate prostatic urethras of different sizes and shapes. The retention rings may be constructed from the same elastomeric compounds used in the first and second terminal ends. According to one aspect, the rings incorporate an elastic member to provide rigidity to the device and to ensure that the device reverts spontaneously to its predetermined configuration from its collapsed state.

[0009] In one embodiment, both the first and second terminal ends are wider than at least some portion of the wall. Under this construction, the wall extending between the terminal ends forms a double funnel or hourglass configuration. Once placed in a patient, this double funnel configuration acts to maintain the stent in position within an open passageway. When placed in the prostatic urethra, for example, one of the first or second terminal ends rests at the bladder end of the prostatic urethra and allows for drainage of urine into the prostatic urethra. The other of the first or second terminal ends sits above

the external sphincter to prevent migration into the bulbous urethra while maintaining drainage through the prostate.

[0010] A lumen may extend between the first and second terminal ends to allow drainage of fluids through the passageway. Alternatively or additionally, drainage may be provided or enhanced by grooves located on the wall. In addition, the wall may define one or more through-holes disposed along its length to provide for fluid communication with the lumen to further facilitate drainage.

[0011] In another embodiment, one of the first and second terminal ends further comprises a dome structure. The dome may define at least one aperture, and terminates in a protuberance. The wall of this embodiment may include at least one annular collar to provide breaking points for the device entering its collapsed state. To further enhance collapsibility, the wall may define one or more slots. The slots may comprise openings through, or concave surfaces along the wall.

[0012] According to one embodiment, the stent of the invention includes a coating material. The coating material may be disposed continuously or discontinuously on the surface of the stent. Further, the coating may be disposed on the interior and/or the exterior surface(s) of the stent.

[0013] The coating material may include, but is not limited to a medicinal composition that leaches into the wall of a body lumen after implantation (e.g. to deliver a therapeutic agent to the body lumen). The coating is preferably a polymeric material, which is generally provided by applying to the stent a solution or dispersion of preformed polymer in a solvent and removing the solvent. Suitable polymeric coating materials, include, but are not limited to polytetraflouroethylene, silicone rubbers, or polyurethanes, all of which are known to be biocompatible. Non-polymeric material may alternatively be used.

[0014] In another aspect, the invention is directed to a delivery system for inserting stents into a body of a patient. In general, the delivery system includes a retractable sheath, a shaft partially disposed within the sheath and a rotatable locking element disposed over the sheath.

[0015] According to one embodiment, the retractable sheath has a wall of a flexible material and proximal and distal portions. As used herein, "distal" refers to an area or direction away from the medical operator inserting the device, while "proximal" refers to an area or direction close to the medical operator inserting the device into the patient. The retractable sheath defines an internal lumen that extends from the proximal to the distal portion. The internal lumen holds the stent in its collapsed state at the distal portion of the sheath. The sheath also defines a first groove and a longitudinal opening through the wall of the proximal portion. The first groove and longitudinal opening are connected and lie perpendicular to one another, forming an "L" or "T" shape.

[0016] Optional features of the sheath include a retraction handle, radiopaque locator bands, and a rounded distal end with a series of small longitudinal slits. The retraction handle may be disposed on the proximal portion of the sheath, and provides a grip to pull on to retract the sheath after insertion into a body of a patient. The radiopaque locator bands may be disposed on the wall of the sheath, and assist medical practitioners in positioning the stent under visualization by X-ray. The rounded distal end facilitates insertion of the stent in the urinary tract. The slits in the rounded distal end facilitate retraction of the sheath after insertion of the delivery system.

[0017] According to one embodiment, the shaft is coaxially disposed within the sheath and slidably movable within the lumen of the sheath. The shaft comprises at least one second groove. The shaft may further comprise an insertion handle, which provides a surface to push on to insert the delivery system into a body of a patient.

[0018] In a further embodiment, the rotatable locking element includes a tongue adapted to engage the first groove of the sheath and the at least one second groove of the shaft. The locking element is disposed over the proximal portion of the sheath.

[0019] When the tongue engages the first groove of the sheath and the at least one second groove of the shaft, relative movement between the sheath and the shaft cannot occur, thereby preventing premature deployment of the stent. To disengage the sheath from the shaft, the locking element is rotated, positioning the tongue in the longitudinal opening of the sheath. This allows relative movement between the shaft and the sheath, and thus allows retraction of the sheath over the shaft to deploy the stent. To disengage the tongue from the at least one second groove of the shaft, a thumb tab may be disposed on the locking element. Downward pressure on the thumb tab lifts the tongue out of the at least one second groove of the shaft. Releasing the tongue from the at least one second groove of the shaft allows the locking element to slide over the sheath.

[0020] The delivery system may include a slidable stop cup disposed on the sheath. The slidable stop cup is used to position the delivery system against the head of the penis of a male patient during insertion of the delivery system into the male urethra. Optionally, the slidable stop cup may be integrated with the locking element to stabilize or secure the positioning of the delivery system and the stent in the urinary tract.

[0021] In other aspects, the invention involves methods of placing stents, such as those previously described. One method of placing these and other collapsible and expandable stents into a body of a patient comprises collapsing the stent, inserting it into the distal portion of the sheath of the delivery system of the invention, inserting the delivery system into the body of the patient, retracting the sheath over the shaft, and removing the delivery system from the body of the patient, thereby deploying the stent within the body. An alternate method of placing the domed stent of the invention comprises providing the domed stent, positioning a conventional guidewire stylet

assembly within the domed stent, inserting the guidewire stylet assembly into a body of a patient, and removing the assembly from the body of the patient, thereby deploying the domed stent within the body.

[0022] In another aspect, the invention involves methods for removing stents of the invention from a body of a patient after they have served their purpose. Removal of the stents of the invention comprises providing a cystoscope and a grasping device, inserting the cystoscope and grasping device into the body of the patient, locating the stent with the cytoscope, attaching the grasping device to the wall of the stent, removing the grasping device attached to the stent from the body, and removing the cystoscope from the body.

[0023] In yet another aspect, the invention involves methods of making the stents and delivery systems of the present invention. A method of making stents of the invention comprises injection molding the stent as one continuous piece. Alternatively, a method of making the domed stent comprises injection molding the body segment and proximal end segment in one mold, separately injection molding the dome in a second mold, and securing the individual components to one another. Similarly, a method of making the delivery systems of the invention comprises extruding the sheath, injection molding the other individual components and securing them together.

[0024] The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description, the drawings, and from the claims.

Brief Description of the Drawings

[0025] In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

[0026] FIG. 1 is a perspective view of one embodiment of the stent of the invention with a double funnel configuration.

[0027] FIG. 2 is a longitudinal cross-sectional perspective view of the stent of FIG. 1.

[0028] FIG. 3 is an enlarged longitudinal cross-sectional front view of the distal end segment of the stent of FIG. 1 with a portion of the elastic member shown in phantom line.

[0029] FIG. 4 is a cross-sectional view of the lower portion of the male abdomen illustrating a portion of the urinary tract with the stent of FIG. 1 positioned in the prostatic urethra.

[0030] FIG. 5 is a side view of an alternate embodiment of the stent of the invention with a domed structure.

[0031] FIG. 6 is a top view of the embodiment of the stent of FIG. 5.

[0032] FIG. 7 is an expanded longitudinal cross-sectional view of the domed structure of the stent of FIG. 5.

[0033] FIGS. 8A-8B are front views of stents according to the invention in two alternate collapsed states.

[0034] FIG. 9 is a longitudinal cross-sectional view of one embodiment of the delivery system according to the invention.

[0035] FIG. 10 is a side view of the delivery system of FIG. 9.

[0036] FIG. 11 is a partial longitudinal cross-sectional view of the slidable stop cup and the locking element engaging a portion of the sheath and a portion of the shaft of the delivery system.

[0037] FIG. 12 is a transversal cross-sectional view of the locking element taken along line A-A of FIG. 11, with the insertion and retraction handles in the background.

[0038] FIGS. 13A-13C show a front view (13A), a side view (13B), and a cross-sectional view (13C) of the locking element of the delivery system.

[0039] FIG. 14 is a partial side view of the delivery system showing the retractable sheath and the locking element of FIG. 9 and with the stent partially deployed.

[0040] FIGS. 15A-15D illustrate a method for placing a collapsible/expandable stent into the prostatic urethra of a male patient using the delivery system of FIG. 9.

[0041] FIG. 16 is a side view of a cystoscope and grasping device extending through a sheath with a locking bridge attached to the sheath and a telescope in phantom line.

[0042] FIG. 16A is a blown-up view in perspective of the tip of the grasping device.

Description

[0043] Stents, according to an illustrative embodiment of the invention, are useful for maintaining the patency of the prostatic urethra. Because the size and shape of this body lumen often varies from patient to patient, the stent is preferably sufficiently flexible to accommodate anatomical differences, while at the same time, sufficiently strong to maintain the prostatic urethra open in response to constrictive forces. Thus, according to the illustrative embodiment, stents of the present invention are therefore generally constructed of flexible biocompatible materials, including, but not limited to silicone, TEFLON® and other PTFE polymers, polyurethane polymers, thermal plastics or malleable metals. Such materials combine the rigidity necessary for maintaining the prostatic urethra open and able to pass fluids while also being soft enough for patient comfort. The flexible material of the stent may be doped with a radiopaque material to

permit visualization by X-ray. Barium sulfate is one example of a suitable radiopaque agent that may be used with stents of the present invention.

[0044] According to a further feature, the stent of the illustrative embodiment is collapsible and expandable, and designed for use in the prostatic urethra of a male patient. Insertion of these and other collapsible and expandable stents into the patient may be accomplished by use of delivery systems according to the present invention, which comprise a retractable sheath, a shaft and a rotatable locking element.

[0045] FIG. 1 depicts one illustrative embodiment of a stent **10**. The stent **10** has a body segment **12** including a wall **14** made of a flexible material and extending between a first terminal end **20** and a second terminal end **24**. The wall **14** has an internal surface **16** and an external surface **18**. In the illustrative stent **10**, the first terminal end **20** is wider than (e.g., has at least one external diameter greater than) at least some portion of the body segment **12** located between the first **20** and second **24** terminal ends.

[0046] In one illustrative embodiment, the first terminal end **20** includes a first retention ring **22** extending axially from the body segment **12**. According to one feature, the first retention ring **22** anchors the stent **10** at the bladder end of the prostatic urethra, above the prostate, after insertion into a patient. In the illustrative stent **10**, the second terminal end **24** is wider than (e.g. has at least one external diameter greater than) at least some portion of the body segment **12** extending between the first and second terminal ends, **20** and **24**, respectively. Illustratively, the second terminal end **24** includes a second retention ring **26** extending axially from the body segment **12**. According to one feature, the second retention ring **26** anchors the stent **10** at the external sphincter end of the prostatic urethra, below the prostate, after insertion into a patient. Additionally, the stent **10** may employ zero, one or two retention rings, such as the retention rings **22** and **26**.

[0047] As skilled practitioners will appreciate, in other embodiments, only one of the terminal ends **20** and **24** may have an external diameter, such as diameter **3** or **7**, that is greater than the external diameter, such as the diameter **5**, of an intermediate portion of the body segment **12**. In the illustrative stent **10**, both the external cross-sectional diameters **3** and **7** of the terminal ends **20** and **24**, respectively, are greater than the external cross-sections diameter **5** of an intermediate portion of location along the wall **14**, between the first and second terminal ends **20** and **24**. This configuration creates a funnel or hourglass shape to facilitate maintaining the stent **10** in position within the prostatic urethra. For example, in one illustrative embodiment, the diameter **5** of the body segment **12** is between about 18 French and about 21 French, while the diameters **3** and **7** of the first and second terminal ends **20** and **24**, respectively, are between about 22 French and about 26 French. By varying the diameters **3**, **5** and **7** and the length of the body segment **12**, the stent **10** may be tailored to the individual needs of particular patients.

[0048] According to the illustrative embodiment, the stent **10** may also be designed according to the individual needs of particular patients in other ways. For example, the total length of the stent **10** may be varied between about 1.0 inch and about 2.5 inches, to accommodate the size of a patient's prostatic urethra, which varies in length from about 0.6 inches to about 3.0 inches. To determine the length of the patient's prostatic urethra, a conventional measuring catheter may be employed.

[0049] According to a further illustrative feature the diameters **3**, **5** and/or **7** may be varied in size, relative to each other, to cause the wall **14** of the body segment **12** to be sloped at various angles. By way of example, for patients with wide prostatic urethras, the ratio of, for example, diameter **3** to diameter **5** may be made sufficiently large to cause the wall **14** to slope slopes sharply in an outward direction to ensure that the double funnel configuration anchors in place within the patient's body. The ratio between the

diameter **7** and the diameter **5** may be similarly configured. In a further embodiment, for patients with narrower internal physiologies, the ratio of diameter **3** to diameter **5** and/or diameter **7** to diameter **5** may be selected to be small enough to avoid the potential discomfort associated with an ill-fitting stent, but large enough to anchor the stent **10** within the patient's body.

[0050] To provide drainage of fluid from a patient's bladder, a lumen **28** may extend through the body segment **12** between the first terminal end **20** and the second terminal end **24**. Alternatively or additionally, drainage may be provided or enhanced by grooves located on the external surface **18** of the wall **14**. Optionally, the wall **14** of the body segment **12** may define one or more through-holes **30** disposed along its length. Through-holes may also be disposed in the first and second terminal ends **20** and **24**, respectively, or in the first and second retention rings **22** and **26**, respectively.

[0051] The through-holes **30** extend through the external surface **18** to the internal surface **16** of the stent **10**, and provide for fluid communication with the lumen **28** to facilitate urinary drainage. As illustrated in FIG. 2, the various through-holes **30** define openings through the wall **14** of the stent **10**, shown in cross section. To avoid tissue in-growth and to maximize drainage, the diameter of the through-holes **30** in the disclosed embodiments is preferably between about 0.06 in. to about 0.12 in.

[0052] The thickness *t* and hardness *h* of the stent **10** affect its collapsible and expandable properties. If the stent **10** is too thick and/or too hard, the body segment **12** will not collapse to permit insertion into a patient's body. If the stent **10** is too thin and/or too soft, it may tear during or after insertion into a patient's body leading to potential medical complications. It may also fail to provide adequate support to the prostatic urethra. The thickness *t*, as shown in FIG. 2, is illustratively between about .01 in. and about .08 in. The hardness *h* is illustratively between about 35 shore A and about 65 shore A, with 50 shore A preferred.

[0053] FIG. 3 shows a cross-sectional view of the first retention ring **22** extending axially from the first terminal end **22**. In one embodiment, the first retention ring **22** is fabricated from the same flexible material as the body segment **12**. As shown in FIG. 3, the illustrative first retention ring **22** includes an annular elastic member **32** to reinforce the first retention ring **22**. The elastic member **32** may be embedded within the flexible material of the retention ring **22** or bound to a surface or groove of the first retention ring **22**. Illustratively, FIG. 3 shows the elastic member **32** embedded within the first retention ring **22**. According to the embodiment of FIG. 3, the elastic member **32** circumscribes the first retention ring **22**.

[0054] The elastic member **32** may also be fabricated from a material having "superelastic" properties. Such a material may include alloys of In—Ti, Fe—Mn, Ni—Ti, Ag—Cd, Au—Cd, Au—Cu, Cu—Al—Ni, Cu—Au—Zn, Cu—Zn, Cu—Zn—Al, Cu—Zn—Sn, Cu—Zn—Xe, Fe_3Be, Fe_3Pt, Ni—Ti—V, Fe—Ni—Ti—Co, and Cu—Sn. In the illustrative embodiment, the superelastic material includes a nickel and titanium alloy, known commonly as Nitinol® available from Memry Corp of Brookfield, CT or SMA Inc. of San Jose, CA. The ratio of nickel and titanium in Nitinol® can vary. One preferred example includes a ratio of about 50% to about 56% nickel by weight. Nitinol® also possesses shape retention properties.

[0055] FIG. 4 is a conceptual diagram depicting an illustrative placement of the stent **10** within a prostatic urethra **38** of a male patient. As seen in FIG. 4, the first terminal end **20** of the stent **10** rests above the prostate, at the bladder end of the prostatic urethra **38**, while the second terminal end **24** of the stent **10** lies below the prostate, above the external sphincter **42**. According to the illustrative embodiment, no part of the stent **10** extends through the external sphincter **42**. Such positioning relative to the external sphincter **42** is preferable to avoid.

[0056] The details of the internal anatomy shown in FIG. 4 include the prostate gland **34**, the urethra **36** (spanning from the penile urethra **37** through the bulbous urethra **39** and to the prostatic urethra **38**), the bladder **40** and the external sphincter **42**. The urethra **36** is the channel that conducts urine from the bladder **40** to the penis **44** for discharge from the body. The inside diameter of the urethra **36** is variable and may typically extend to about 0.8 in. The prostatic urethra **38** is a segment of the urethra **36** that tunnels through the prostate gland **34** and joins the prostate gland **34** to the urethra **36**. Urine flows from the bladder through the prostatic urethra **36** to the bulbous urethra **39** and to the penile urethra **37** out of the body. The external sphincter **42** controls the flow of urine from the bladder **40**.

[0057] FIG. 5 depicts a stent **46** according to another illustrative embodiment of the invention. The stent **46** has a body segment **48**. The body segment **48** is formed from a wall **50** of flexible material extending between a first terminal end **54** and a second terminal end **62**. As shown in FIG. 5, the first terminal end **54** has external cross-sectional diameter **39**. Similarly, the second terminal end **62** has an external cross-sectional diameter **43**. The stent **46** also has at least one intermediate external cross-sectional diameter **41**. According to the illustrative embodiment, both external diameters **39** and **43** are larger than the intermediate external diameter **41** to facilitate anchoring the stent **46** in place within the body of a patient. According to a further embodiment, a portion **53** of the body segment **48** located adjacent to the first terminal end **54** tapers to increase the cross-sectional diameter **39** of the first terminal end **54**. Similarly, a portion **66** of the body segment **48** located adjacent to the second terminal end **62** flares to increase the cross-sectional external diameter **55** of the second terminal end **62**. To further anchor the stent **46** in place within a patient's body, the second terminal end **62** includes a retention ring **64** extending axially from the body segment **48**. Illustratively,

the wall **50** has an external surface **52** and an internal surface (not shown) defining a lumen **51**.

[0058] According to the illustrative embodiment of FIG. 5, the collapsible and expandable nature of the stent **46** is enhanced by annular collars **68**, varying of the wall thicknesses *t* and providing at least one slot **70** disposed along the body segment **48**. The annular collars **68** lie along various sections of the body segment **48** and serve as breaking points to radially collapse the stent **46**. The wall thickness *t* of the body segment **48** decreases towards the annular collars **64**. In one illustrative embodiment, the portion of the wall **50** that lies near the annular collars **64** has a *t* value of about 0.010 inches to about 0.30 inches with about 0.20 inches preferred. As the wall **50** extends away from the annular collars, the *t* value increases to between about 0.035 inches to about 0.055 inches, with about 0.04 in. preferred.

[0059] In one illustrative embodiment, the slots **70** are formed as concave inner or outer surfaces in the wall **50** of the body segment **48**. In an alternative embodiment, the slots **70** are formed as through openings in the wall **50**. In FIG. 5, the slots **70** are formed as through openings in the wall **50**. These slots **70** enhance the collapsible properties of the stent **46**. In addition, where the slots **70** are formed as concave surfaces, the surface area of the stent **46** is increased, allowing swollen prostate tissue to occupy these surfaces to further anchor the stent **46** in position within a body of a patient, without favoring encrustation of the stent **46**. The size of the slots **70** is not confined to predetermined dimensions, but may vary, provided collapsibility is enhanced and the stent **46** retains an expandable structure. Optionally, a suture **55** may loop through a slot **70** defining an opening at the end segment **62** to facilitate removal of the stent **46**.

[0060] According to a further feature, the first terminal end **54** includes a hollow dome **56** extending axially from the body segment **48**. Rounded shoulders at the top of the dome **56** facilitate insertion of the stent **46** into small openings, such as the male

urethra **36**. The dome **56** includes at least one through-hole **58** adapted for urine transfer into the lumen **51**.

[0061] The lumen **51** extends through the body segment **48** from the first **62** to the second end **54** to provide fluid communication between the at least one through-hole **58** and the urethra. Bodily fluid from the bladder drains into the at least one through-hole **58** residing in the dome **56** and into the body segment **48** to be released through the first terminal end **62** into the urethra.

[0062] The dome **56**, with its through-hole configuration, acts as a filter, allowing fluids and small harmless solid materials, such as blood clots, to pass, while preventing large blood clots and other solid materials, such as calculi or stone debris, from occluding the lumen and interrupting the passage of fluids through the stent **46**. In one embodiment, the through-holes **58** have a diameter between about 0.06 inches and about 0.1 inches, with about 0.09 inches preferred. In one illustrative embodiment, the dome **56** includes two to six through-holes **58**. In one particular embodiment, the dome **56** includes four through-holes. The through-holes may be disposed at various intervals (regular or irregular) along the surface of the dome. For example, FIG. 6 shows four through-holes **58** disposed at four different locations along the dome **56**. In the illustrative embodiment of FIG. 6, the centers of the four through-holes **58** lie at 0°, 90°, 180°, and 270° angles along the periphery of the dome **56**. The through-holes **58** may, however, lie at any combination of angles along the periphery of the dome **56**.

[0063] As shown in FIGS. 5 and 6, the dome **56** may terminate in a protuberance **60**, which facilitates insertion of the stent **46**. The protuberance **60** is useful, for example, when the stent is inserted with a conventional guidewire stylet assembly, known to those of skill in the art. As seen in FIG. 7, the protuberance **60** may define a small lumen **61** for insertion of a guidewire through the stent **46**. The lumen **61** of the protuberance **60** is

preferably between about 0.039 inches and about 0.049 inches in diameter to accommodate conventional guidewires.

[0064] According to the illustrative embodiment of the invention, after the stents **10** and **46** have been collapsed, delivery systems of the invention may be used to introduce these and other collapsible/expandable stents into a body of a patient. FIGS. 8A-8B depict the domed stent **46** in its collapsed state in two possible configurations. In FIG. 8A, the wall **50** of the body segment **48** of the stent **46** is collapsed along the slots **70**. In FIG. 8B, the stent **46** is folded in half on itself along line B-B.

[0065] FIG. 9 shows one embodiment of a delivery system **80** used to introduce these and other collapsible and expandable stents into a body of a patient. In general, the delivery system **80** comprises a retractable sheath **82**, a shaft **84**, and a rotatable locking element **86**.

[0066] The retractable sheath **82** has a proximal portion **88** and a distal portion **90**. The sheath **82** defines an internal lumen that extends from the proximal portion **88** to the distal portion **90** for housing a portion of the shaft **84** and holding the stent **10**. The sheath **82** further defines a first groove **81** transversal to the length of the sheath **82**.

[0067] The retractable sheath **82** is made of a wall **85** of flexible material. Preferred flexible materials include, a high density polyethylene or a polypropylene based extrusion. According to the illustrative embodiment, the thickness of the wall **85** of the retractable sheath **82** is between about 0.050 inches and about 0.060 inches. According to one embodiment, the thickness of the wall **85** is about 0.055 inches. In one embodiment, the inner diameter of the sheath **82** is between about 0.280 inches and about 0.340 inches. According to one embodiment, the inner diameter of the sheath **82** is about .312 inches. According to a further embodiment the inner diameter of the sheath **82** is sized to accommodate the stent **10** in its collapsed state.

[0068] A retraction handle **97** may be disposed on the proximal portion **88** of the sheath **82**. The retraction handle **97** is adapted to proximally retract the sheath **82**. The retraction handle **97** may include two finger grips **99** and **101**, which allow medical practitioners to more easily retract the sheath **82** by pulling back on the finger grips **99** and **101**.

[0069] The shaft **84** includes a proximal end **98** and a distal end **100**, and further includes at least one second groove **83**. The at least one second groove **83** may be a notch limited to the top surface of the shaft **84**, in which case the shaft **84** is rotatable with the locking element **86**. Alternatively or additionally, the at least one second groove **83** may be a carved-out section of the shaft **84** that wraps circumferentially around the shaft **84** along a 90°, 180°, 270°, or 360° path, in which case the shaft **84** need not be rotatable.

[0070] The shaft **84** is preferably about 10 in. in length, and is preferably at least twice as long as the stent **10** being deployed. Thus, the length of the shaft **84** varies depending on the length of the stent **10** and the patient's internal anatomy. The distal end **100** of the shaft **84** may expand radially to form a plunger shape that abuts the stent **10**.

[0071] An insertion handle **102** may be disposed on the proximal end **98** of the shaft **84**. The insertion handle **102** is adapted to insert the delivery system **80** into the body of a patient. FIG. 10 is a top view of the insertion handle **102** with the retraction handle **97** lying behind it in the background.

[0072] The rotatable locking element **86** is disposed over the proximal portion **88** of the sheath, and comprises a tongue **114**. The tongue **114** is adapted to engage the first groove **81** of the sheath **82** and the at least one second groove **83** of the shaft **84**.

Referring to FIG. 11, the illustrative locking element **86** includes a proximal end **106**, a distal end **108**, a top portion **110** and a bottom portion **112**. In FIG. 11, the tongue **114** is

disposed on the distal end **108** under the top portion **110** of the locking element **86**, but may be positioned elsewhere on the locking element **86** provided it can engage both the first groove **81** of the sheath **82** and the at least one second groove **83** of the shaft **84**. When the delivery system is in the locked position, the tongue **114** engages the first groove **81** of the sheath **82** and the at least one second groove **83** of the shaft **84**. A more detailed view of the locking element **86** and its mode of operation is shown in FIGS. 12 and 13A-13C.

[0073] FIG. 12 is a cross-sectional view of the distal end **108** of the locking element **86** taken along line A-A of FIG. 11. In FIG. 12, the tongue **114** is engaging the first groove **81** of the sheath **82** and the at least one second groove **83** of the shaft **84**. This configuration prevents relative movement between the sheath **83** and the shaft **84** during insertion of the delivery system into a body of a patient. FIG. 12 also shows the insertion handle **102** and the retraction handle **97** in the background.

[0074] FIG. 13A is a front view of one embodiment of the locking element **86**. In this embodiment, opposing "S" shaped slits **150** in the top surface of the locking element **86** define the thumb tab **116**. The top surface of the locking element **86** further defines two longitudinal slits **152** that lie on either side of the tongue **106**. A pivot point **154** sits between the "S" shaped slits **150** and the longitudinal slits **150**, allowing a medical practitioner to lift the tongue **106** by depressing the thumb tab **116**.

[0075] The locking element **86** may be reinforced with a series of ribs **156**, which comprise areas of increased internal wall thickness. In FIG. 13A, the ribs **156** are shown in phantom. The ribs **156** provide added circumferential strength to the locking element **86** during rotation and engagement of the tongue **106**.

[0076] FIG. 13B is a side view of the locking element of FIG. 13A taken along line B-B. As shown more clearly in FIG. 13B, the ribs **156** comprise raised internal

surfaces of the interior of the locking element **86**. One of the ribs **156** reinforces the thumb tab and extends to the tongue **114**.

[0077] FIG. 13C is a cross-sectional view of FIG. 13A, taken along line C-C. In FIG. 13C, the ribs **156** lie at regular intervals in a quadrant configuration. The ribs **156** need not, however, lie at regular intervals or in any particular configuration, emphasis instead being placed on sufficient reinforcement for the locking element **86**. FIG. 13C also shows the tongue **114** and the longitudinal slits **150**. The central hole **158** that surrounds the tongue **114** of FIG. 13C allows the locking element **86** to slide over the shaft **84** after the tongue **114** is disengaged from the sheath **82** and shaft **84**.

[0078] After insertion of the delivery system into the body of the patient, the sheath **82** is withdrawn over the shaft **84** to deploy the stent **10**. Referring to FIG. 14, a more detailed view of the structure of the retractable sheath **82** is provided. The retractable sheath **82** defines an internal lumen **89**, which extends from the proximal portion **88** to the distal portion **90** and contains the stent **10** within the distal portion **90**.

[0079] The retractable sheath **82** further defines the first groove **81** and a longitudinal opening **94** through the wall **85** of the proximal portion **88** of the sheath **82**. The longitudinal opening **94** comprises a proximal end **96** and a distal end **93**. The proximal end **96** of the longitudinal opening **94** is connected to and lies perpendicular to the first groove **81**, forming an "L" or "T" shape. A portion of the shaft **84** may be seen through the distal end **93** and proximal end **96** of the longitudinal opening **94** of the sheath **82**.

[0080] To disengage the tongue **114** from the first groove **81** of the sheath **82**, the locking element **86** is rotated one-quarter turn clockwise to position the tongue **114** within the longitudinal opening **94** of the sheath **82**, allowing relative movement between the sheath **82** and the shaft **84**. FIG. 14 depicts the tongue **114** positioned within the longitudinal opening of the sheath **82**. When the at least one second groove **83** is limited

to a notch on the top surface of the shaft **84**, rotation of the locking element **86**, rotates the shaft **84** to maintain the tongue **114** within the at least one second groove **83** of the shaft **84**. When the at least one second groove **83** of the shaft **84** wraps circumferentially around the shaft **84**, rotation of the locking element **94** need not rotate the shaft **84** to maintain the tongue **114** within the at least one second groove **83**, as the tongue **114** is merely re-positioned around the circumferential length of the same at least one second groove **83** of the shaft **84**.

[0081] To facilitate insertion and withdrawal of the sheath **82** in and from the patient, the distal portion **90** of the sheath **82** may terminate in a rounded autramatic tip, which may comprise any number of slits **91** from two to six slits with four slits typical. The slits come together at the end of the rounded tip in a star-like configuration. The slits **91** facilitate proximal retraction of the sheath **82** by opening widely over the stent **10** during retraction over the shaft **84**.

[0082] At least one radiopaque locator band **95** may be disposed on the wall **85** of the sheath **82**. For example, two radiopaque locator bands **95** may be used to mark the stent **10** contained within the sheath **82** (such as shown in FIGS. 15A-D). Radiopaque locator bands **95** guide the medical practitioner (e.g. the physician) in positioning the stent **10** within a body of a patient under visualization by X-ray. The radiopaque locator bands **95** may be comprised of heavy metals, such as steel, tantulum, gold rings or the like.

[0083] In an alternate embodiment, a thumb tab **116** may be disposed between the proximal and distal ends **106** and **108** of the top portion **110** of the locking element **86** as shown in FIG. 11. The thumb tab **116** may be effaced within the profile of the locking element **86**, or it may rise radially and outwardly at an angle with the tongue **114** to provide for greater pivoting angles to the tongue **114**. Referring to FIG. 11, the tongue **114** of this embodiment is retractable from the grooves **83** of the shaft **84**, and the locking

element **86** is slidable along the length of the shaft **84**. Downward pressure on the thumb tab **116** raises the tongue **114** out of the at least one second groove **83** of the shaft **84**. This embodiment further comprises a slidable stop cup **104** disposed distal to the locking element **86** on the shaft **84**. In addition, the grooves **83** comprise about 40-50 grooves spaced at approximately 10 grooves per in., spanning approximately half of the length of the shaft **84** at its distal end **100**.

[0084] The locking element **86** may be used to distally advance the slidable stop cup **104** along the length of the shaft **84**. After disengaging the tongue **114** from the first groove of the sheath **82** by rotating the locking element **86** to position the tongue **114** in the longitudinal opening **94**, and disengaging the tongue **114** from the at least one second groove **83** by depressing the thumb tab **110**, the locking element **86** becomes slidable along the length of the shaft **84**.

[0085] The slidable stop cup **104** is used to position and stabilize the delivery system **80** against a body of a patient before deploying the stent **10**. For example, after inserting the delivery system **80** into the prostatic urethra **38**, the medical practitioner rotates the locking element **86**, depresses the thumb tab **116**, and slides the locking element **86** along the shaft **84** to advance the stop cup **104** along the shaft **84** until the stop cup **104** lies against the meatus in the head of the penis. At this point, the thumb tab **116** is released, re-engaging the tongue of the locking element **86** into one of the plurality of second grooves **83** of the shaft **84**, thereby locking the slidable stop cup **104** in place. The tongue **106** does not, however, re-engage the first groove **81** of the sheath **82**, but rather remains in the longitudinal opening **94** of the sheath **82** to allow relative movement between the sheath **82** and the shaft **84**.

[0086] FIGS. 15A-15D illustrate a method of inserting a stent of the invention into the body of a patient with a delivery system of the invention. To load the stent **10** into the delivery system **80**, manual or automated pressure is exerted on the body

segment **12** and the proximal and distal end segments **20** and **24** of the stent **10** to collapse it (as in FIGS. 8A-B), and the collapsed stent **10** is placed within the sheath **82** through an opening in its proximal portion **88** or its distal portion **90**. The collapsed stent **10**, may be so placed by the manufacturer prior to sale, or by the medical practitioner prior to insertion.

[0087] With the stent **10** in place, the delivery system **80**, in its locked configuration, is introduced into the body of a male patient through the meatus **117** in the head **118** of the penis **120** into the urethra **36** as shown in FIG. 15A. In doing so, a medical practitioner may hold the head **118** of the penis **120** in one hand and exert pressure in a distal direction on the insertion handle **102** with the other hand. Under X-ray vision, the medical practitioner may use the radiopaque locator bands **95** to help position the delivery system **80** through the urethra, so that the distal portion **90** of the sheath **82**, containing the two radiopaque locator bands **95**, is located within the prostatic urethra **38** surrounded by the prostate gland **34** and above the external sphincter **42**.

[0088] During insertion, the delivery system **80** is in its locked configuration to prevent premature deployment of the stent **10**. The tongue **114** of the locking element **86** engages the first groove **81** of the sheath **82** and one of the plurality of grooves **83** of the shaft **84** to prevent relative movement between the sheath **82** and the shaft **84** (FIG. 11).

[0089] The locking element **86** may also be used to advance the slidable stop cup **104** against the head **118** of the penis **120**. To position the slidable stop cup **104,** the locking element **86** is rotated one-quarter turn clockwise to disengage the tongue **106** from the first groove **81** of the sheath **82**, thereby positioning the tongue **106** in the longitudinal opening **94** of the sheath **82** (FIG. 14). The thumb tab **116** is then depressed, disengaging the tongue **106** from one of the plurality of grooves **83** of the shaft **84**, so that the locking element **86** becomes slidably movable along the length of the shaft **84**. This

allows the medical practitioner to use the locking element **86** to distally advance the slidable stop cup **104** to the head **118** of the penis **120**.

[0090] Referring to FIG. 15B, the locking element **86** has been advanced distally along the length of the delivery system **80** exposing the first groove **81** of the sheath **82**, and positioning the slidable stop cup **104** at the head **118** of the penis **120**. Once the slidable stop cup **104** is in this position, the thumb tab **116** is released, re-engaging the tongue **106** into another of the plurality of grooves **83** of the shaft **84**, preventing movement of the slidable stop cup **104** backwards. The locking element **86** thereby maintains the slidable stop cup **104** against the head **118** of the penis **120**, and secures the distal end **90** of the delivery system **80** within the prostatic urethra **38**.

[0091] As FIG. 15C illustrates, after the slidable stop cup **104** is positioned against the head **118** of the penis **120**, the sheath **82** is withdrawn, exposing and releasing the stent **10**. To withdraw the sheath **82**, the locking element **86** is rotated to position the tongue **106** within the longitudinal opening **94** of the sheath **82**, allowing relative movement between the sheath **82** and the shaft **84**. The medical practitioner then proximally withdraws the retraction handle **97** by positioning some fingers on the finger grips **99** and **101** and exerting pressure in a proximal direction. As the retraction handle **97** is slowly retracted, the sheath **82** moves backward, thereby partially deploying the stent **10** within the prostatic urethra **38** of the patient, as shown in FIG. 15C.

[0092] To fully deploy the stent **10** within the prostatic urethra **38**, the sheath **82** is completely withdrawn over the stent **10** by the retraction handle **97**, and the delivery system **80** is then removed from the body. Under these circumstances, the stent **10** reverts to its expanded geometry. FIG. 15D shows the expanded stent **10** deployed within the prostatic urethra **38** of the male patient, once released from the delivery system.

[0093] Once the stent has served its purpose, it is removed to avoid infection. Removal of the stent may be accomplished through use of a cystoscope and a conventional grasping device, shown in FIG. 16. FIG. 16 shows a grasping device **122** with forward forceps **124** disposed within a sheath **126** secured to a bridge **128** adapted to receive a cystoscope **127**. A detail of the forward forceps **124** is illustrated in FIG. 16A.

[0094] In addition to the forward forceps **124**, the grasping device **122** further comprises an axially elongated shaft **130** and scissors-like handles **132** disposed co-planar and at an angle with the elongated shaft **130** at a proximal portion **134** of the assembly. The scissors-like handles **132** are used to manipulate the forward forceps **124**. The diameter of the sheath **126** must be large enough to accommodate the elongated shaft **130**. The cytoscope **127** comprises a telescopic lens **136** for viewing a body lumen, and a port **138** for irrigating or draining the body lumen.

[0095] To remove stents of the invention from a body of a patient with the cytoscope grasping device assembly, a medical operator inserts the assembly into the urethra of the patient, locates the stent disposed within the prostatic urethra through the telescopic lens **136,** manipulates the scissors-like mechanism **132** to close the forward forceps **124** on a wall of the stent, pulls the grasping device **122** proximally to remove the stent from the body of the patient, and removes the cystoscope **127** from the body.

[0096] Alternatively, removal of the stents of the invention may occur by proximally withdrawing the thread of suture material **55** (FIG. 5) until the stent **46** is pulled through the meatus of the head of a penis. As shown in FIG. 15D, the thread of suture material **55** is looped and threaded through an opening in the wall of the stent **10**, and extends through the urethra to the exterior of the body where it can be easily grasped.

[0097] One illustrative method of manufacturing stents according to the illustrative embodiment of the invention (FIGS. 1 and 5) includes injection molding each stent of the invention as a single continuous piece or separately injection molding the

various components, such as the dome and the body segment and securing these individual components together by suitable means, including but not limited to solder, weldment, or adhesive.

[0098] Injection molding includes providing an injection mold that profiles the different structural features of the stents, injecting liquid silicone or thermal plastic into the mold, allowing the mold to cure, and removing the cured structure from the injection mold. To provide an internal lumen, a core pin may be positioned down the center of the injection mold. The injection mold may further include protrusions extending from the inner surfaces of the mold for incorporating through-holes or slots into the stent. Alternatively, these features may be added to the stent after it is cured. To reinforce the stents with an elastic member, such as nitinol, the mold may incorporate the elastic member in the appropriate position, or the elastic member may be introduced through a small axial lumen incorporated into the mold after the stent is cured, or the elastic member may be taped or glued to the stent.

[0099] According to one embodiment, method of making the delivery system of the invention includes extruding the sheath, independently injection molding other individual parts, such as the shaft, locking element, slidable stop cup and insertion and retraction handles, and securing these individual parts together by suitable means, including but not limited to solder, weldment, or adhesive to assemble the delivery system.

[0100] Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and scope of the invention. Accordingly, the invention is to be defined not only by the preceding illustrative description.

What is claimed is: